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08/06/2003

JACKSON WALKER
112 EAST PECAN ST.
SUITE 2100
SAN ANTONIO, TX 78205

EXAMINER

THALER, MICHAEL H

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 08/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/994,321

Applicant(s)

O'HEERON ET AL.

Examiner

Michael Thaler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Each point 40A is described as being "conical" (page 4, line 1). However, a "cone", by definition, is "A surface generated by a straight line, passing through a fixed point and moving along the intersection with a fixed curve" (Webster's II New Riverside Dictionary, underlining added). That is, a cone must have a curved base. Also, the cross-section of a cone taken in a horizontal plane (i.e. a plane perpendicular to a line from the base to the apex) must have a curved perimeter. It does not appear from figure 2 (i.e. the general planar shape of insert blade 37 and that a blade, by definition is generally planar) and the related description in the specification that the "cone" of point 40A has a cross-section (taken in a horizontal plane) that has a curved perimeter. Therefore, the exact shape of points 40A is unclear. Also, edges 40B are described as being "beveled" (page 4, line 2). It is unclear if this means 1) that one edge 40B (for example, the edge 40B which is closest to head 38) is angled relative to the other edge 40B to form the bevel or 2) that each edge 40B is formed by two surfaces (one along the top of the wing and the other along the

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bottom of the wing) which converge toward each other to form the bevel.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The scope of the claims is unclear for the reasons set forth above.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 4, as best understood, are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Danks et al. (5,545,150). Danks et

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al. disclose housing 40, cannula 13, obturator assembly 12 comprising a shaft having a piercing end (figures 7-9) with a piercing tip with an upper face (e.g. the left concave surface 94 as seen in figure 7A) and a lower face (e.g. the right concave surface 94 as seen in figure 7A) which taper from the shaft to form a non-conical, blunt end 92, handling end 17 and wing elements (the side portions of blade 81 which protrude laterally outward from the sides of the distal end 51 of shield 15 as best seen in figures 8B and 9B) having conical-shaped points (Shoulders 88, which are points since each shoulder is formed at the sharp corner of an obtuse angle as best seen in figures 8B and 9B. These shoulders 88 meet the term "conical-shaped" as best understood in the unclear claims since they each have tapering sides which converge at an apex.) and beveled lateral edges 91. Alternatively, it would have been obvious that shoulders 88 are broadly conical-shaped for the reason set forth above.

Claims 2, 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Danks et al. (5,545,150) in view of Fortier (6,106,539). As to claim 2, Danks et al. fail to disclose the blunt head and wing elements being metal. However, Fortier teaches that a trocar obturator may be made of metal (col. 3, lines 64-67) in order to provide strength to it. It would have been obvious to make the Danks et al. the blunt head and wing elements metal so that it too would have this advantage. As to claim 3, Danks et al.

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disclose the blunt head being plastic (col. 8, lines 5-9) but fail to disclose the wing elements being plastic. However, Fortier teaches that a trocar obturator may be made of plastic (col. 3, lines 64-67) in order to provide strength to it while apparently reducing its cost. It would have been obvious to make the Danks et al. the wing elements plastic so that it too would have this advantage. As to claim 5, Danks et al. fail to disclose the piecing tip as being removable from the shaft. However, Fortier teaches that a piercing tip of a trocar should be removable from the shaft in order to make it cost effective (col. 1, lines 44-46). It would have been obvious to make the Danks et al. piecing tip removable from the shaft so that it too would have this advantage.

Claims 6-8 are free of any rejection based upon the prior art of record.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703)308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are

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(703)305-3590 for regular communications and (703)305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht
August 1, 2003


MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731